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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application No.

10/791,270

Confirmation No.: 8940

First Named Inventor

Masaaki NOMURA

Filed

: March 3, 2004

TC/A.U. Examiner 1615 (To Be Assigned)

Docket No.

: 100598.53322US

Customer No.

: 23911

Title

Pharmaceutical Hard Capsule Containing Inorganic

Substance

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT UNDER 37 C.F.R § 1.97 AND 1.98

Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

Sir:

This supplements the Information Disclosure Statement submitted in the above-identified application on July 26, 2004.

In accordance with the duty of disclosure under 37 C.F.R. § 1.56, Applicant hereby notifies the U.S. Patent and Trademark Office of the documents which are listed on the attached Form PTO-1449 and which the Examiner may deem relevant to patentability of the claims of the above-identified application.

In compliance with the concise explanation requirement under 37 C.F.R. § 1.98(a)(3) for foreign language documents, Applicant encloses herewith a copy of a corresponding European Search Report dated June 23, 2005 citing documents AA-AH together with an English-language version (if not already included) of that portion of the Search Report indicating the degree of relevance found by the foreign office.

The present Information Disclosure Statement is being filed before the mailing date of the first Office Action on the merits. Furthermore, I hereby Page 1 of 2

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PATENT

certify that each item of information contained in this Information Disclosure

Statement was first cited in any communication from a foreign patent office in a

counterpart foreign application not more than three months prior to the filing of

this Information Disclosure Statement and therefore no fee under 37 C.F.R.

 $\S 1.17(p)$ is required.

The submission of the listed documents is not intended as an admission

that any such document constitutes prior art against the claims of the present

application. Applicant does not waive any right to take any action that would be

appropriate to antedate or otherwise remove any listed document as a competent

reference against the claims of the present application.

If necessary, the paper should be considered as a petition for consideration

of the Information Disclosure Statement under 37 C.F.R. § 1.97(d)(1) and that

the petition fee set forth in 37 C.F.R. § 1.17(p) in accordance with 37 C.F.R.

§ 1.97(d)(2) should be charged to Deposit Account 05-1323, Attorney Docket

No.: 100598.53322US.

Respectfully submitted,

August 25, 2005

Registration No. 32,169

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PTO/SB/08a (08-03)

Approved for use through 07/31/2006. OMB 0651-0031
U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE work Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Complete if Known Substitute for form 1449A/PTO **Application Number** 10/791,270 INFORMATION DISCLOSURE Filing Date March 3, 2004 STATEMENT BY APPLICANT First Named Inventor Masaaki NOMURA Art Unit 1615 Examiner Name (To Be Assigned) (use as many sheets as necessary) Attorney Docket Number 100598.53322US

of

Sheet

U.S. PATENT DOCUMENTS								
Examiner Initials'	Cite No. ¹	Document Number Number-Kind Code ² (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear			
	AA	US- 03/0124188 A1	07/03/2003	Burnside et al.				
	AB	US-2001/0051188 A1	12-13-2001	Ullah et al.				
		US-						
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FOREIGN PATENT DOCUMENTS								
Examiner Initials'	Cite No.1	Foreign Patent Document Country Code ³ -Number ⁴ -Kind Code ⁵ (if known)	Publication Date	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T [®]		
	AC	WO 00/76520 A1	12-21-2000	Hanmi Pharm Co., Ltd.				
	AD	WO 00/59475 A1	10-12-2000	Lipocine, Inc.				
	AE	WO 99/44614 A1	09-10-1999	DaeWoong Pharmaceutical Co., Ltd.				
	AF	DE 101 44 557 A1	03-27-2003	Bayer AG				
	AG	WO 03/037379 A1	05-08-2003	Degussa AG				
	АН	EP 0 722 732 A1	07-24-1996	Mitsui Toatsu Chemicals, Inc.				

Examiner		Date	
Signature		Considered	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. 1 Applicant's unique citation designation number (optional). 2 See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. 3 Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). 4 For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. 5 Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. 6 Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.